UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next of Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	**Case No. 3:05-0444**
v.	)	**Judge Aleta A. Trauger**
PFIZER INC., et al,	)	
Defendant.	)	

EXPERT WITNESS STATEMENT OF PETER D. DONOFRIO, M.D.

My name is Peter D. Donofrio. I am a neurologist at Vanderbilt here in Nashville. In this case I was asked to give my expert opinion on the effectiveness and safety of Neurontin for treating chronic neuropathic pain conditions, the relationship of Mr. Smith's pain conditions to his suicide, and whether Neurontin played any role in causing Mr. Smith's suicide.

Let me begin by explaining my background and qualifications. I am a medical doctor and Professor of Neurology at Vanderbilt University School of Medicine. Neurology is the medical specialty devoted to diagnosing and treating diseases, disorders, and injuries to the nerves. That includes the central nervous system, the brain and spinal cord, as well as the peripheral nervous system, the nerves that branch out from the spinal cord throughout the rest of the body.

At Vanderbilt University Medical Center, I am Chief of the Neuromuscular Section and the Director of the electromyography, or "EMG," Laboratory. EMG is a medical diagnostic procedure that we use in neurology to examine the nerves, similar to the way that X-rays, CT scans, and similar techniques are used to examine other parts of the body.

At Vanderbilt, I spend more than half of my time in patient care, and the remainder on research, teaching, and committee responsibilities. I evaluate between 40 and 50 patients each week with neuromuscular disorders, which are problems involving the nerves, muscles, or both.

Many of my patients have neuropathic pain. "Neuropathic" pain is caused by a variety of metabolic diseases or injury to the nerves. Common causes of neuropathic pain include diabetes, alcohol abuse, vitamin deficiencies, trauma to nerves and nerve roots, spine diseases, and spinal cord injuries. Neuropathic-pain symptoms include the feeling of pins and needles, burning and shooting pain as well as stabbing or throbbing pain. The goal of treatment is to reduce the severity of symptoms, improve functionality and ultimately, quality of life.

I graduated from college at the University of Notre Dame in Notre Dame, Indiana in 1972, and then completed medical school at The Ohio State University School of Medicine in Columbus, Ohio in 1975. After medical school, I completed a Medicine Residency at Good Samaritan Hospital in Cincinnati, Ohio and a Neurology Residency and Neuromuscular Fellowship at the University of Michigan.

I taught medicine at the University of Michigan for four years, Wake Forest University for more than 20 years, and have been on the faculty at Vanderbilt since 2006. In all of those positions, my work has included not only teaching medical students and new doctors in an academic or classroom setting, but also treating patients with neurological disorders and painful conditions at each of those universities' medical centers.

I am board certified in three medical specialties: Internal Medicine, Neurology, and Electromyography. I have special interests in the areas of peripheral neuropathy, diabetic neuropathy, inflammatory neuropathies, all of which cause the "neuropathic" form of pain I

mentioned earlier, as well as myasthenia gravis, and amyotrophic lateral sclerosis, also known as "ALS" or Lou Gehrig's disease.

During my career, I have written and published more than 80 peer-reviewed medical articles, 70 abstracts, and 10 book chapters. I am a member of the Editorial Board of *Muscle & Nerve*, which is a leading journal in my field, neurology. I have given more than 250 invited lectures.

Over the past 22 years, I have been awarded research grants to study painful diabetic neuropathy, chronic inflammatory neuropathies, amyotrophic lateral sclerosis, and myasthenia gravis. I have been listed as one of the Best Doctors in America every year since 1994 and am a member of America's Top Physicians.

A copy of my curriculum vitae, or "CV," that lists more details about my education and professional background is marked as Ex. 255.

In order to reach my conclusions in this case, I reviewed medical records of the patient, as well as medical reports and manuscripts on Neurontin, also known by its generic name, gabapentin. I also relied a great deal on my own clinical experience in prescribing Neurontin for many patients with chronic pain conditions over the past 15 years. As a neurologist and professor of neurology, I regularly study, diagnose, and treat neuropathic and chronic pain conditions, evaluate the potential risks and benefits of pain medications, and treat patients who have pain conditions and, often, accompanying illnesses including depression.

[Demonstrative: Summary of Opinions]

My major opinions about this case, based on a reasonable degree of medical certainty, are summarized on this chart, and can be summarized as:

- Neurontin is a safe and effective treatment for neuropathic pain, and is widely regarded in neurology as one of the most useful medication options for treating chronic neuropathic pain.
- The labeling, or professional package insert, for Neurontin approved by FDA at the time of Mr. Smith's death adequately communicated the potential benefits and risks of Neurontin to doctors.
- The dosage of Neurontin that Mr. Smith was prescribed at the time of his death was relatively low and probably was insufficient to provide significant pain relief.
- Mr. Smith's suicide is most likely attributable to his chronic pain, his depression, and feelings of hopelessness after being informed shortly before his death that there were no additional treatment options for his severe, chronic pain.

In order to explain the basis for my conclusions, I need to first provide some background information about neuropathic pain, how it is commonly treated, and Neurontin's role in treatment of neuropathic pain.

Neuropathic pain is extremely difficult to treat. Many patients do not respond adequately to the first or second medication prescribed. Mr. Smith's case is a typical example, in that he had been treated with many different medications over the years. Patients with neuropathic pain are often taking other medications for pain and other medical conditions, so the potential for drug interactions is common. Doctors need to minimize the risk that medications prescribed for neuropathic pain symptoms might interact with other medications that the patient may be taking for diabetes, heart problems, or other conditions. For this reason, Neurontin is attractive because it has very limited potential for drug interactions. In addition, Neurontin is often preferred over alternative pain medicines such as narcotics for three major reasons. First, patients with neuropathic pain commonly develop a tolerance for narcotic pain medications. There is also potential for abuse of narcotic drugs. These are significant concerns with long-term use of narcotics, but Neurontin does not have these problems. Third, Neurontin is often more effective for neuropathic pain.

I have treated thousands of patients suffering from neuropathic pain. When I treat my patients, I base my prescribing decisions on several factors. Specifically, in choosing which medications to prescribe, I rely on my own experience, the experience of my colleagues, side-effect profiles of a particular medication, evidence-based medicine (for example, results from large clinical studies), and the unique needs and characteristics of my patients. I have never relied on detailing or advertising from pharmaceutical companies or their sales representatives when deciding whether to prescribe a medication. And I should add that no one from Pfizer or Warner-Lambert has ever promoted the off-label use of Neurontin to me or in an educational forum that I have attended.

Based on all those considerations, in my opinion Neurontin is a safe and effective treatment for neuropathic pain. For years, Neurontin has been considered one of the drugs of choice for treating neuropathic pain. Before Neurontin was introduced in 1994, for the previous several decades, doctors had been treating neuropathic pain with older anti-epileptic drugs as well as drugs such as tricyclic antidepressants. Beginning in the mid-1990s, shortly after Neurontin became available, doctors began to try, and report success, using Neurontin to treat neuropathic pain. The early success with Neurontin was especially welcome news because Neurontin had a better side-effect profile than many of the medications available at that time and drug interactions were not common.

Over time, Neurontin has become a "first-line" treatment for neuropathic and other forms of chronic pain because it is effective for many patients, well-tolerated, and has a limited potential for abuse and drug interactions.

In my own clinical experience, Neurontin can be effective in relieving neuropathic pain in doses as low as 100 mg twice or three times per day, but this is not common. In most

situations of neuropathic pain, patients need dosing of at least 600 mg three times per day, or 1,800 mg/day total. I have prescribed up to 4,800 mg/day with success in relieving symptoms of neuropathic pain. As I will explain later, Mr. Smith's dosage at the time of his death was 900 mg/day, which is well below the dosage that most patients need to see meaningful relief.

In addition to my clinical experience with gabapentin, there is a large body of clinical studies that support the effectiveness of gabapentin in treating a variety of different neuropathic and chronic pain conditions. These include both studies sponsored by the manufacturers of Neurontin, Warner-Lambert's Parke-Davis division, and later Pfizer, as well as a number of studies conducted by independent researchers.

The clinical studies supporting Neurontin's effectiveness include research where Neurontin was compared directly to an inactive pill, called a placebo control; other studies where Neurontin was compared to a known effective medication; as well as a number of what we call "open-label" studies, which means studies where Neurontin is studied by itself, without any other drug or placebo for comparison. Scientifically speaking, the placebo-controlled studies are considered the most convincing evidence of a medication's true effects, including both its beneficial or therapeutic effects as well as its side effects.

The placebo controlled studies supporting Neurontin's safety and effectiveness in the form of neuropathic pain known as post-herpetic neuralgia led to FDA approval of that use in 2002. Those studies are described in the FDA package insert for the medication.

The medical literature includes reports of placebo-controlled studies in other forms of neuropathic pain, such as diabetic neuropathy, mixed neuropathic pain, pain from spinal cord injury, neuropathic pain from cancer treatment, and other forms of pain. The vast majority of these studies succeeded in showing that Neurontin was effective, and I have found the

medication effective clinically in many of my own patients with the same or related conditions.

Again, the important point of the research from my perspective as a neurologist is that Neurontin is a useful medication for significant numbers of patients with neuropathic or related chronic pain conditions. Although we have no universally-effective medication for neuropathic or chronic pain conditions, and each patient's best medication or combination of medications has to be determined on an individual basis, Neurontin is one of most useful options, and a medication that I often turn to first for these patients.

It is important to realize that most of the medications we prescribe for neuropathic pain conditions are used on an "off-label" basis. There are many different kinds of neuropathic pain. In European countries, Neurontin and other drugs have been approved by drug-regulatory agencies for "neuropathic pain" in general. But here in the United States, FDA has never approved any drug for a broad "neuropathic pain" indication. Instead, FDA has approved only a few medications for a few specific kinds of neuropathic pain – Neurontin's approval for post-herpetic neuralgia being one of them.

For many patients, who either have some form of neuropathic pain for which there is no FDA-approved medication, or for patients who have tried an FDA-approved medication without success, treatment by necessity has to be "off-label." Prescriptions of Neurontin for any neuropathic pain condition other than post-herpetic neuralgia, for example, are considered "off-label." Doctors prescribe a number of other medications for neuropathic pain on an off-label basis as well. For example, tricyclic antidepressants are effective, but have never been approved by FDA for any form of neuropathic pain. Prescribing tricyclic antidepressants and other medications on an "off-label" basis is very common in neurology and chronic pain treatment,

and in fact is considered the standard of care in the medical community here and everywhere else I have practiced.

Let me now turn to my opinions on the adequacy of the Neurontin labeling – the package insert approved by FDA to convey information to doctors about the medication.

In my opinion, the labeling for Neurontin that was in effect in 2004 when Mr. Smith was prescribed Neurontin was adequate to warn physicians of the risks and benefits of using the medication. I am familiar with the FDA Alert issued in January 2008 about the agency's evaluation of suicidality risk with the class of anti-epileptic drugs, as well as the Advisory Committee proceedings held later that year. The FDA proceedings do not change my opinion and, in fact, have not changed my prescribing behavior. I have been prescribing Neurontin for approximately fifteen years. No patient has ever reported suicidality to me in connection with his or her Neurontin use and I am not aware of any patient of mine committing suicide while taking Neurontin.

There is no convincing and reproducible scientific data supporting a conclusion that Neurontin causes suicide. The meta-analysis conducted by the FDA of 11 different anti-epileptic drugs does not prove that Neurontin causes suicidality. In fact, the Neurontin-specific data in the FDA's report specifically show that there is no statistically significant increased risk of suicidality with Neurontin use. The work done by Dr. Robert D. Gibbons, Ph.D. confirms that the data show no increased risk of suicidality in patients who take Neurontin. In my opinion, there was never any basis for Pfizer to have changed the labeling that FDA had approved in 1993 and 2002 to add information or warnings about suicidality.

To summarize, it is my opinion that Neurontin is a safe and effective medication, one of the drugs of choice for treating neuropathic pain, and the drug of choice when treating patients who are taking other medications that have potential for drug interactions.

Let me now turn to my opinions about Mr. Smith's specific case, and the reasons that I believe explain his tragic decision to end his life.

Richard Smith's medical records show that he suffered from increasingly severe, chronic, and debilitating neuropathic pain in the last years of his life. As a clinician, I treat individuals like Richard Smith and have found that it is difficult, and sometimes impossible, to reduce their severe pain.

[Demonstrative: Mr. Smith's Pain Complaints]

This chart summarizes the pain complaints that appear in Mr. Smith's medical records from the late 1980s to 2004. There are many of them. Let me highlight some of the issues that are especially significant to me.

Mr. Smith's pain issues began in the late 1980s with jaw and pelvic pain. Mr. Smith experienced pain in his left knee and it was replaced with a prosthetic knee in 1993.

In 1996, Mr. Smith developed pain in his right hip, ultimately resulting in a right hip replacement in May 1996.

In 1998, Mr. Smith had a right knee replacement.

In January, 1999, Mr. Smith complained of left shoulder pain.

In September 2000, he again complained of knee pain.

In 2001, he complained of pain in his shoulder blades, neck, chest, and insomnia. In May 2001, Mr. Smith's primary care physician, Dr. Cato, prescribed the antidepressant amitriptyline 10 mg at bedtime. Amitriptyline, sometimes known by its trade name Elavil, is often prescribed

on an off-label basis to treat neuropathic pain, or to help patients with painful conditions sleep, or both.

[**Demonstrative: February 6, 2003, Tennessee Orthopedic Alliance Notes - Dr. Smith**]

Mr. Smith's pain continued to worsen and was aggravated in January 2003 when he injured himself while fixing water pipes at his home.

[**Demonstrative: February 27, 2003, Neurological Surgeons' Notes - Dr. Hampf**]

In February, 2003, Mr. Smith was told by Dr Hampf, a neurological surgeon, that he needed surgery to repair a disc in his back.

[Demonstrative: March 11, 2003 Nurses Notes—Dr. Berklacich]

Dr. Hampf referred Mr. Smith to Dr. Berklacich, a neurosurgeon, to perform the surgery. Mr. Smith ultimately decided not to have the surgery performed because his pain was so severe that he wanted to undergo surgery earlier than Drs. Hampf and Berklacich's schedules would allow.

[Demonstrative: April 1, 2003, Dr. McCombs' Operative Report]

Dr. Paul McCombs performed Richard Smith's surgery on April 1, 2003 (DPM-15). Initially, Mr. Smith seemed pleased with the results of his surgery.

[Demonstrative: May 2, 2003, Neurosurgical Associates Notes – Dr. McCombs]

Unfortunately, by the end of April 2003, the pain returned and in May 2003, Dr. McCombs' office staff documented a phone call from one of Richard Smith's daughters stating that Mr. Smith "wished he could die because of pain and depression."

[Demonstrative: May 15, 2003, Dr. Cato's Notes]

The next month, in June 2003, Mr. Smith's primary care physician, Dr. Cato, diagnosed him with anxiety and depression and prescribed Lexapro (an antidepressant) to treat him. This was prior to Richard Smith's use of Neurontin. That is very important in understanding this case: Mr. Smith had expressed the wish to die because of pain and depression, before he ever used any Neurontin, and he had been diagnosed with depression before he ever took Neurontin.

From early 2003 until his death in May 2004, Richard Smith's pain became increasingly severe and debilitating. Mr. Smith's medical records document his increasing pain, depression, and hopelessness in the year prior to his suicide, as well as the fact that his chronic pain was resistant to treatment, which I believe contributed to his depression and suicidal ideation. The next several charts show a sampling of the records that I believe are important in understanding what Mr. Smith was going through during the last year of his life.

- May 5, 2003, McCombs (000006-34NEA-00001). Dr. McCombs' records note that Mr. Smith was experiencing "new symptoms of increased leg pain."

- June 27, 2003, Cato (000006-30HMA-00065, 66). Dr. Cato had diagnosed Mr. Smith with anxiety and depression related to pain. This is common in patients with the kinds of chronic pain problems that Mr. Smith was suffering. Dr. Cato had prescribed two antidepressants, Lexapro and desipramine, and as we see here, Mr. Smith had improved, but had ran out of the Lexapro and stopped it after just six weeks. There is no indication that Mr. Smith's depression was ever treated from this point forward.

- January 5, 2004, McCombs (000006-34NEA-00002). Dr. McCombs' records document that Mr. Smith was reporting "shocks in his back." Again, this is a new type of pain complaint, different from those that Mr. Smith had experienced in prior years.

- January 20, 2004, Cato (000006-42HMA-00097). Dr. Cato diagnosed Mr. Smith with "post-laminectomy syndrome." That usually means painful symptoms related to priorback surgery.

- February 12, 2004, Mackey (000006-32TOA-00004). Mr. Smith saw another orthopedist, Dr. Mackey, for a second opinion about his severe leg pain. The record indicates that Mr. Smith's pain was "getting worse" and that it was not helped by medication. Mr. Smith had not taken Neurontin by this point in time, so the reference to other medications not helping is to other pain medications that his doctors had tried to treat his pain.

- February 23, 2004, Cato (000006-42HMA-00089-90). Mr. Smith told Dr. Cato that it "hurts to move."

- February 25, 2004, Mackey (000006-32TOA-00005). Dr. Mackey's records indicate that, in addition to back and leg pain, Mr. Smith was also complaining of knee pain and radicular pain.

- March 1, 2004 (000006-96MNP-00010). The Police Report prepared shortly after his death indicates that on March 1, Mr. Smith had expressed suicidal ideation to his daughter, Cindy Smith, similar to the remarks made in May of the preceding year about "wishing he could die because of pain and depression." Again, Mr. Smith had not taken Neurontin by this time.

- March 9, 2004, Mackey (000006-32TOA-00007). Dr. Mackey's records indicate that Mr. Smith was complaining of severe pain, and had to use a wheelchair to get into Dr. Mackey's office. It was suggested to the family that Mr. Smith be evaluated by a psychiatrist (Dr. West) over concerns about his mental health. This recommendation was not followed through. Mr. Smith was never treated by Dr. West or any other psychiatrist. This is the same day that Mr. Smith was first prescribed and actually ingested Neurontin, and we see that by this time, Mr. Smith had already been depressed for some time, had already expressed suicidal thoughts on at least two occasions, and had already developed mental-health problems serious enough that professional help was being recommended to the family.

- March 24, 2004, McCombs (000006-34NEA-00003). Dr. McCombs' records note that Mr. Smith is in so much pain that Mrs. Smith scheduled a follow-up appointment with Dr. McCombs within a week. According to Dr. McCombs' nurse, Mr. Smith was told at this point that he had no options for pain relief other than medication and epidural steroid injections. The nurse told Mr. Smith to increase his daily Neurontin from 600 to 900 mg/day, which is still only about half of the 1,800 mg daily dose that most patients, in my experience, need for neuropathic pain.

- March 29, 2004, Mackey (000006-32TOA-00006). Dr. Mackey told one of Mr. Smith's daughters that he did not think that surgery would help ease Mr. Smith's pain.

- March 31, 2004, McCombs (000006-34NEA-00003). Dr. McCombs concurred with Dr. Mackey that Mr. Smith was not a candidate for any type of operative intervention and recommended conservative therapy. Dr. McCombs confirmed this in his deposition.

- April 15, 2004, Berklacich (000006-52FMB-00052). Dr. Berklacich, a spine surgeon, refused to treat Richard Smith.

- Meanwhile, what is happening outside the doctors' offices in April and May 2004? Ruth Smith testified in her deposition that Richard Smith spent most of his days laying around the house trying to stay out of pain. It is clear that Mr. Smith's pain has become so severe by this point that he is functionally debilitated, unable to carry out activities that he would normally do.

- May 4, 2004, Physical Therapist (000006-35UMC-00076). About nine days before he died, according to records from his physical therapy, Mr. Smith rated his pain as 7/8 on a scale of 1 to 10, which is described as "excruciating."

- May 5, 2004, McCombs (000006-34NEA-00003). About eight days before his death, Richard Smith called Dr. McCombs office complaining of pain with no relief from medications and reported that the physical therapy was not helping him. Dr. McCombs confirmed this in his deposition. According to Mr. Smith's own handwritten notes, he was also told that McCombs' office "had nothing to offer" him for pain.(Deposition of Ruth Smith taken on April 12-13, 2007, Exhibit 1)

- May 6, 2004, Physical Therapist (000006-35UMC-00076). About seven days before his death, Mr. Smith decided to stop physical therapy because he did not think he was improving. He also "voiced concern that something serious [was] going on."

- May 10, 2004, Dentist (000006-19CLW-00001). Mr. Smith told his dentist that an end to his pain seemed to be hopeless. He also told his dentist that he wished he had never had back surgery, said that he could no longer cut the grass or work on cars, and that he felt "useless."

- May 13, 2004, Suicide note. Richard Smith himself writes: "Pain has taken over my mind and body. I need back surgery, left and right rotator cuffs, right biceps torn, back surgery to correct pain in the legs. Forgive me, I cannot go on like this! I cannot have my body, the temple of the Holy Spirit cut on anymore. I have talked to God all night and he understands."

In my opinion, these medical records, as well as Mr. Smith's heartbreaking suicide note, show that he had been fighting a losing battle against a host of debilitating and painful conditions, from multiple major surgeries to replace hip and knee joints, to back injury and surgery. He was experiencing severe chronic pain that left him unable to live his life the way he wanted to and no treatment seemed to help.On top of that ,he had developed, serious depression and suicidal thinking – all long before he ever used Neurontin.

When we look more closely at Mr. Smith's use of Neurontin, it becomes clear, in my opinion, that Neurontin played no role whatsoever in his ultimate decision to end his life.

Richard Smith was first prescribed Neurontin on May 5, 2003 (000006-34NEA-00001). However, according to Mrs. Smith's deposition testimony and Dr. McCombs' records, Mr. Smith chose not to take Neurontin at that time. Dr. McCombs' records indicate that although

Neurontin was recommended, Mr. Smith "wanted to wait until absolutely necessary" before starting the medication. (000006-34NEA-00002).

[Demonstrative: March 9, 2004, First Neurontin Prescription]

The first time Richard Smith was actually prescribed and took Neurontin was on March 9, 2004. Dr. Mackey prescribed 300 mg to be taken twice a day. According to the medical records, that prescription was filled on March 9, 2004 at Eckerd Pharmacy.

On March 24, 2004, one of Dr. McCombs' nurse practitioners, Pam Krancer, prescribed Neurontin for Richard Smith at 300 mg, to be taken three times per day.

[Demonstrative: Photographs of Neurontin Sample Packs and Bottle; Exs. 249, 250]

I cannot tell from Mr. Smith's medical records whether he actually took the Neurontin prescribed for him as frequently as he was directed to take it. He filled a prescription written March 9, 2004 by Dr. McCombs for sixty (60) 300 mg tablets. That is the only prescription the records show he ever filled for Neurontin. The bottle found after his death, shown here, contained at least 15 unconsumed tablets. He also apparently received some sample packages that contained three 300 mg tablets in each packet. Six packets apparently remained unconsumed after his death.

If he followed the directions from his providers, Mr. Smith would have taken two tablets each day from March 9 to March 24. That would total 32 tablets over that first 16 days. On March 24, Nurse Krancer told him to increase his dosage from 600 to 900 mg day, that is, from two up to three 300 mg tablets. So if he followed her instructions, he would have taken three tablets for the 50 day period from March 25 to May 13, or 150 tablets total over that period. Altogether, he would have had to take 182 tablets (the 32 plus the 150) between the initial prescription and his death.

If we do the math, given that he had at least 15 tablets remaining in the bottle, he used at most 45 tablets from the bottle of 60 that he got at the pharmacy March 9. Those 45 tablets, which I assume he did in fact ingest, would have gotten him through the period March 9-24, when he was told to take two each day, and then for about another five days at the three-tablets per day dosage Nurse Krancer told him to take, or to about the first of April, about six weeks before his death on May 13.

For him to have taken three tablets per day as directed over the thirty days in April plus the first 13 days in May, about a 43 day period, he would have had to take a little more than 130 more tablets. Since we have already taken account of the pills in the bottle, that means he would have to have been given more than 40 of these three-tablet sample packages by someone, and that he would have had to use those exclusively and for some reason stop using the tablets in the bottle he had gotten from the pharmacy.

The bottom line is that he either received a very large number of sample packages, of which there is no documentation in his records, or else he either skipped many doses that he was supposed to have taken, or stopped taking Neurontin well before the time he died.

Even if we assume Richard Smith had been taking the medication as prescribed, in my clinical judgment, his dose may have been too low to offer him any relief from his pain. Mr. Smith was prescribed a low dose of Neurontin -- 600 mg/day to 900 mg/day, as compared with the effective dosage range reported in the labeling for Neurontin of 1,800-3,600 mg/day. It is likely that this dose was sub-therapeutic for him and that he was not achieving adequate pain relief from this dose of Neurontin or from his other pain medications. This opinion is supported both by my clinical experience and the published, peer-reviewed neurological literature.

Based on my review of the medical records in this case, it is my opinion to a reasonable degree of medical certainty, that Neurontin did not cause Mr. Smith's suicide. Mr. Smith's suicide is likely attributable to his chronic severe pain, depression, and hopelessness that was triggered by being told that there were no additional treatment options for his pain.

Mr. Smith's doctors began telling him in March 2004 that there was no treatment for his pain other than medication and physical therapy. The doctors' statements were reinforced on May 5, 2004, seven days prior to Mr. Smith's suicide, when he was told by Dr. McCombs' office that there was nothing that could be done to relieve his pain.

Mr. Smith's choice to end his life is one that is made by patients, especially elderly patients, who are made hopeless by severe chronic pain that does not respond to treatment.

[Demonstrative: Quote from Juurlink publication]

The risk of suicide in elderly patients with chronic pain is recognized in the medical literature. As explained by Dr. David Juurlink and others, in an article published in the journal Archives of Internal Medicine in June 2004, *"[t]he risk for suicide among patients [elderly] with severe pain merits particular attention. Patients with severe pain and inadequate analgesia [pain relief] may view suicide as a means of escape from suffering."*

This scenario is what I believe happened in this case. Based on the medical records, Mr. Smith's suicide note, in which he explains that pain had taken over his mind and body, and that he simply could not go on like that, and statements made by Mrs. Smith during her 911 call, when she described how terrible his pain had become in the days leading up to his death, it is my opinion that the best explanation for Richard Smith's suicide centers on his chronic pain, depression, and hopelessness. I do not believe his death can be blamed on Neurontin.